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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/382,242      | 08/24/1999  | DAN E. ROBERTSON     | DIVER1180-1         | 4972             |

20985 7590 12/18/2002

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[REDACTED] EXAMINER

PROUTY, REBECCA E

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1652     |              |

DATE MAILED: 12/18/2002

LS

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |   |
|------------------------------|--------------------------------------|---|
| <b>Office Action Summary</b> | Application No.<br><b>09/382,242</b> | Applicant(s)<br><b>Robertson et al.</b> |
|                              | Examiner<br><b>Rebecca Prouty</b>    | Art Unit<br><b>1652</b>                 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1)  Responsive to communication(s) filed on Oct 2, 2002

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

#### Disposition of Claims

4)  Claim(s) 21-33 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) 21 is/are allowed.

6)  Claim(s) 22-33 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1)  Notice of References Cited (PTO-892)

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

6)  Other: \_\_\_\_\_

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A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 7/26/02 has been entered.

Claims 1-20 have been canceled. Claims 21-26 and newly presented claims 27-33 are still at issue and are present for examination.

Applicants' arguments filed on 7-26-02, paper No. 21, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 22-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is confusing in the recitation "comprising a nucleic acid sequence consisting of a sequence..." as the

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combination of the open language of the term "comprising" with the closed language of the term "consisting of" makes it unclear if the claimed probe could have any additional nucleic acid sequence beyond that which specifically hybridizes to SEQ ID NO:23 or its complement or not.

Claim 26 is indefinite in the recitation of "stringent conditions" as page 10 of the specification defines "stringent conditions" as conditions under which hybridization will occur only if there is at least 90% identity between two nucleic acids and page 13 of the specification defines "stringent conditions" as conditions under which hybridization will occur only if there is at least 95% identity between two nucleic acids. As the specification recites two differing definitions of the same term and in the art what is considered stringent varies widely depending on the individual situation as well as the person making the determination, the claim is indefinite as it is unclear how homologous to the sequence of SEQ ID NO:23, a sequence must be to be included within the scope of the claim.

Claim 27 is indefinite in the recitation of "specifically hybridizes to a nucleic acid having at least 95% identity to SEQ ID NO:23" as it is unclear how a nucleic acid can specifically hybridize to more than one nucleic acid sequence as specifically

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hybridize in the art means hybridizes to a particular nucleic acid sequence but not to other different sequences.

Claims 22-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of oligonucleotide probes which comprise a sequence which specifically hybridizes to SEQ ID NO:23, its complement or to a nucleic acid having 95% identity thereto.

The specification does not contain any disclosure of the structure and function of all oligonucleotide probes which comprise a sequence which specifically hybridizes to SEQ ID NO:23, its complement or to a nucleic acid having 95% identity thereto. The genus of probes that comprise a sequence which specifically hybridizes to SEQ ID NO:23, its complement or to a nucleic acid having 95% identity thereto is a large variable genus with the potentiality of encoding many different proteins. Therefore, many structurally and functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only SEQ ID NO:23 which is insufficient to put one of skill in the art in

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possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).

Claims 22-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a probe consisting of a fragment of SEQ ID NO:23 which will hybridize to SEQ ID NO:23 under stringent conditions and optionally a detectable label, does not reasonably provide enablement for any probe which specifically hybridizes to any nucleic acid having 95% identity to SEQ ID NO:23 under any conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 27 (and Claims 22-25 and 28-32 which depend therefrom) is so broad as to encompass any probe which comprises a nucleic acid which specifically hybridizes to any nucleic acid having 95% identity to SEQ ID NO:23 under any conditions while Claim 26

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encompasses any probe which comprises a nucleic acid which specifically hybridizes to SEQ ID NO:23. The specification teaches a use of only probes which will specifically hybridize to SEQ ID NO:23 (to identify organisms having esterase function) as the specification has not identified any use for the vast number of nucleic acids having 95% identity thereto. Only a very small number of such polynucleotides will encode esterase proteins and the positions within a sequence where modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. Furthermore, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. Thus one of skill in the art would not know which of the vast numbers of sequences having 95% identity to SEQ ID NO:23 would be useful, such that probes which would specifically hybridize thereto would be useful. Furthermore, designing probes which would specifically detect any particular sequence under any conditions would require undue experimentation

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as under low stringency conditions this would likely be impossible while under higher stringencies the structural requirements of the probe would vary depending on not only the hybridization conditions to be used but also the type of material to be tested. Without knowledge of what nucleic acids must be distinguished from the target of interest may be present in the material to be tested one of skill in the art could not determine number of mismatches to the target sequence a probe could have and still hybridize specifically to the target sequence. As such it is highly unpredictable whether a probe which will specifically hybridize to any particular target can be made and it would require undue experimentation to make and use the entire scope of the claimed probes. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of DNAs having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (703) 308-4000. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Rebecca Prouty  
Primary Examiner  
Art Unit 1652